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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/734,752

12/11/2000

Janet A. Warrington

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09/01/2004

EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/01/2004

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,752

Applicant(s)

WARRINGTON ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants response, filed on June 22, 2004. Applicants have canceled all previous claims and have added new Claims 10-12. Claims 10-12 each represent independent and distinct inventions and have been subjected to the restriction requirement below. The restriction requirement was necessitated by Applicants amendments to the claims.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim 10, drawn to a method for diagnosing endometrial cancer in endometrial tissue comprising obtaining a gene expression profile from the endometrial tissue sample wherein expression of the following genes are measured: KIAA0367, KIAA0119, platelet activating factor acetylhydrolase 1B gamma-subunit, UDP-galactose transporter related isozyme, HMG-1 and Lamin-B, classified in class 435, subclass 6, for example.
 - II. Claim 11, drawn to a method of diagnosing endometrial adenocarcinoma by measuring the gene expression in the first endometrial sample of each of the following genes: MIF, cyclin A1, MRG1, HOX1, Alpha 2 collagen type VI, Adducin, Cyclin B and PKC zeta, classified in class 435, subclass 6, for example.
 - III. Claim 12, drawn to a method of diagnosing endometrial clear cell carcinoma comprising measuring the amount of gene expression of each of the following

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genes: calponin, caldesmon, keratin K17, ESE-1b, HMG1, LAMB3, lamin SB3, osteopontin, and decorin, classified in class 435, subclass 6, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I- III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods of diagnosing disease using patentably distinct genes that differ in structure and function. Each Group is drawn to measuring the gene expression of a combination of patentably distinct genes that are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Furthermore, Group I would require searching for methods of measuring expression of KIAA0367, KIAA0119, platelet activating factor acetylhydrolase 1B gamma-subunit, UDP-galactose transporter related isozyme, HMG-1 and Lamin-B; Group II would require searching for methods of measuring expression of MIF, cyclin A1, MRG1, HOX1, Alpha 2 collagen type VI, Adducin, Cyclin B and PKC zeta; and Group III would require searching for methods of measuring expression of calponin, caldesmon, keratin K17, ESE-1b, HMG1, LAMB3, lamin SB3, osteopontin, and decorin, and as such, would require an undue burden on the examiner if not restricted.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their recognized divergent subject matter and because inventions I-III require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

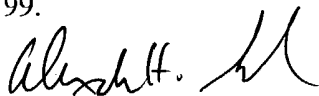
If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

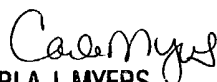
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Alexander H. Spiegler
August 30, 2004



CARLA J. MYERS
PRIMARY EXAMINER